ABBOTT

Corporate Regulatory Affairs

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August 18, 1999

The Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: Medical Devices; Draft Guidance on Quality Systems Inspections Technique [Docket No. 99D-1269]

Dear Sirs or Madams:

Abbott Laboratories submits the following remarks in response to the Agency's request for comments on the above-named subject and docket. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 56,000 people and serving customers in more than 130 countries.

1. *Management Controls, page 8, paragraph 5.* In the second paragraph of this section, the handbook refers to whether or not quality issues are known by executive-level management, and that this suggests that quality audits are not being performed at a sufficient frequency. Executive management knowledge of quality issues is not directly related to audit frequency. Many other quality measurement systems exist and are being used.[1] Further, the awareness of everyday manufacturing issues by executive-level management varies considerably from company to company. In this regard we recommend that the term "executive-level" be stricken from the last sentence.

[1] Quality measurement systems include those used and described by various authors specifically Juran and Gyrna in "Quality Planning and Analysis", third edition, McGraw Hill, 1993.

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2. *Management Controls, page 8, paragraph 6.* The last sentence in the second paragraph, which is underscored, appears to place too much emphasis on the importance of the quality audit function by asserting that without an audit, there is no assurance that the "manufacturer is consistently in a state of control."

   A. Quality Audits are an important part of the Quality System, but no more so than many of the other parts. The lack of an audit function is a regulatory concern but the emphasis and underscoring implies that audits are the central part of every quality control system. Given that the device GMP's and the ISO 9000 guidelines recognize more than 20 elements of a quality system, we believe this sentence should not be highlighted.

   B. The Agency may wish to revise the wording of the last sentence due to the existence of many documented closed-loop systems which quantify the manufacturing state of control. Those systems include: statistical process control or SPC; control charts of which there are more than 20 types, including Shewhart control chart methods; and the many variations of statistical controls such as p charts, np charts, etc.

3. *Design Controls and risk analysis, pages 11 - 13.* Investigators should be advised to use a single standard for understanding a firm's risk management procedures. The use of ISO/IEC 14971, "Application of Risk Management to Medical Devices" is recommended and should be included in the final version of this draft. If companies are judged against different and varying standards, confusion will result.

4. *CAPA, page 18, paragraph 3.* FDA directs its investigators to "determine if the firm is capturing and analyzing data regarding in-conformance product." This seems to conflict with comment #160 in the preamble to the device GMP's published on October 7, 1996 in which FDA said:

   > "it was not FDA's intent to require that processes unrelated to an existing non-conformity be analyzed. Instead, Section 820.100(a)(1) requires an analysis of those items listed that could be related to the problem."

The value of such analysis should be checked against the original comment in the preamble. Analysis of in-specification data is a worthy QA task but the handbook should not direct or lead FDA investigators into judging the effectiveness of the manufacturer's quality system regarding the handling of all possible data.

Yours truly,

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cc: Tim R. Wells, FDA, CDRH (HFA-332)